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Remarks:

Amendments to the claims:

Claims 1, 3-14 and 26 are pending in this application. By this Amendment, claim 1 is amended.

No new matter is added to the application by this Amendment. Support for the features added to claim 1 can be found within the specification, as originally filed, at, for example, paragraphs [0091] and [0098] of U.S. Patent Publication No. 2008/0136055 (hereinafter "the '055 publication") for the present application.

Regarding the rejection of claims 1, 3-5, 7-9 and 26 under 35 USC 102(b) as allegedly being anticipated by or, in the alternative under 35 USC 103(a) as allegedly obvious over U.S. Patent No. 5,382,377 to Raehse et al. (hereinafter "Raehse"):

Applicants traverse the Examiner's rejection of the foregoing claims as allegedly being anticipated by Raehse.

Prior to discussing the relative merits of the Examiner's rejection, the applicant points out that unpatentability based on "anticipation" type rejection under 35 USC 102(b) requires that the invention is not in fact new. See *Hoover Group, Inc. v. Custom Metalcraft, Inc.*, 66 F.3d 299, 302, 36 USPQ2d 1101, 1103 (Fed. Cir. 1995) ("lack of novelty (often called 'anticipation') requires that the same invention, including each element and limitation of the claims, was known or used by others before it was invented by the patentee").

Anticipation requires that a *single reference* [emphasis added] describe the claimed invention with sufficient precision and detail to establish that the subject matter existed in the prior art. See, *In re Spada*, 911 F.2d 705, 708, 15 USPQ2d 1655, 1657 (Fed. Cir. 1990).

The principle of "inherency," in the law of anticipation, requires that any information missing from the reference would nonetheless be known to be present in the subject matter of the reference, when viewed by persons experienced in the field of the invention.

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However, "anticipation by inherent disclosure is appropriate only when the reference discloses prior art that must necessarily include the unstated limitation, [or the reference] cannot inherently anticipate the claims." *Transclean Corp. v. Bridgewood Servs., Inc.*, 290 F.3d 1364, 1373 [62 USPQ2d 1865] (Fed. Cir. 2002); *Hitzeman v. Rutter*, 243 F.3d 1345, 1355 [58 USPQ2d 1161] (Fed. Cir. 2001) ("consistent with the law of anticipation, an inherent property must necessarily be present in the invention described by the count, and it must be so recognized by persons of ordinary skill in the art"); *In re Robertson*, 169 F.3d 743, 745 [49 USPQ2d 1949] (Fed. Cir. 1999) (that a feature in the prior art reference "could" operate as claimed does not establish inherency).

Thus when a claim limitation is not explicitly set forth in a reference, evidence "must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill." *Continental Can Co.*, 948 F.2d at 1268. It is not sufficient if a material element or limitation is "merely probably or possibly present" in the prior art. *Trintec Indus., Inc. v. Top-U.S.A. Corp.*, 295 F.3d 1292, 1295 [63 USPQ2d 1597] (Fed. Cir. 2002). See also, *W.L. Gore v. Garlock, Inc.*, 721 F.2d at 1554 (Fed. Cir. 1983) (anticipation "cannot be predicated on mere conjecture respecting the characteristics of products that might result from the practice of processes disclosed in references"); *In re Oelrich*, 666 F.2d 578, 581 [212 USPQ 323] (CCPA 1982) (to anticipate, the asserted inherent function must be present in the prior art).

Moreover, the undersigned reminds the Examiner that the determination of obviousness under § 103(a) requires consideration of the factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1 [148 USPQ 459] (1966): (1) the scope and content of the prior art; (2) the differences between the claims and the prior art; (3) the level of ordinary skill in the pertinent art; and (4) secondary considerations, if any, of nonobviousness. *McNeil-PPC, Inc. v. L. Perrigo Co.*, 337 F.3d 1362, 1368, 67 USPQ2d 1649, 1653 (Fed. Cir. 2003). There must be some suggestion, teaching, or motivation arising from what the prior art would have taught a person of ordinary skill in the field of the invention to make the

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proposed changes to the reference. *In re Fine*, 837 F.2d 1071, 1075, 5 USPQ2d 1596, 1600 (Fed. Cir. 1988). But see also *KSR International Co. v. Teleflex Inc.*, 82 USPQ2D 1385 (U.S. 2007).

A methodology for the analysis of obviousness was set out in *In re Kotzab*, 217 F.3d 1365, 1369-70, 55 USPQ2d 1313, 1316-17 (Fed. Cir. 2000) A critical step in analyzing the patentability of claims pursuant to section 103(a) is casting the mind back to the time of invention, to consider the thinking of one of ordinary skill in the art, guided only by the prior art references and the then-accepted wisdom in the field. Close adherence to this methodology is especially important in cases where the very ease with which the invention can be understood may prompt one "to fall victim to the insidious effect of a hindsight syndrome wherein that which only the invention taught is used against its teacher."

It must also be shown that one having ordinary skill in the art would reasonably have expected any proposed changes to a prior art reference would have been successful. *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200, 1207, 18 USPQ2d 1016, 1022 (Fed. Cir. 1991); *In re O'Farrell*, 853 F.2d 894, 903-04, 7 USPQ2d 1673, 1681 (Fed. Cir. 1988); *In re Clinton*, 527 F.2d 1226, 1228, 188 USPQ 365, 367 (CCPA 1976). "Both the suggestion and the expectation of success must be founded in the prior art, not in the applicant's disclosure." *In re Dow Chem. Co.*, 837 F.2d 469, 473, 5 USPQ2d 1529, 1531 (Fed. Cir. 1988).

The Patent Office alleges that Raehse teaches or suggests each and every feature recited in claims 1, 3-5, 7-9 and 26. Applicants respectfully disagree with the allegations by the Patent Office.

Raehse fails to disclose an extrusion process in which the proportion of cleaning or water softening composition particulates remaining in the solid state during extrusion is greater

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than 20% and includes a citrate salt having a lower limit particle size of 150 μm as required by amended claim 1.

In contrast, Raehse discloses an extrusion process in which the entire extruded composition is rendered into a liquid state during extrusion. Raehse describes an extruded composition as being plasticized. When an extruded composition is described as being plasticized, it must be assumed that this entire composition is converted into a liquid form. Specifically, Raehse discloses:

Under the shearing effect of the extruder screws, the premix is compacted under pressures of 50 to 200 bar and, more particularly, under pressures of 80 to 180 bar, plasticized, extruded in the form of thin strands through the perforated die in the extruder head and, finally, the extrudate is size-reduced by means of a rotating blade, preferably to spherical or cylindrical granules. (see col. 5, lines 35-42 of Raehse)

Applicants have found that enhanced dissolution control of tablets is obtained by an extrusion of a composition having a high proportion of solid citrate based particulate matter having a lower limit particle size of 150 μm .

As discussed in paragraph [0008] of the '055 publication, the extrusion of hard, crystalline materials has previously been avoided. Extrusion is best suited for materials having a plastic mechanical behaviour, i.e., materials which at least partially melt in the extrusion process. By at least partially melting, the problems of extruder abrasion are avoided. Hence, hard crystalline materials are not extruded due to extruder abrasion issues. However, in the present invention, it has been found that the problem of extruder abrasion has been surprisingly overcome (see paragraph [0093] of the '055 publication).

At best, Raehse discloses extrusion of certain solid materials, such as zeolite materials. However, it should be appreciated that typically such zeolite materials are not abrasive in an extrusion process because of their diminutive particle size (typical zeolite average particle size is less than 50 μm). Also zeolites have lubricious properties because zeolites

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are clay type materials and are not as abrasive as certain other materials, particularly citrate salts having a lower limit for its particle size of 150 μm . It has been found that the problem of extruder abrasion in the extrusion of the presently claimed citrate salt having a lower limit particle size of 150 μm has been surprisingly overcome. Moreover, the present claims are allowable over the teachings of Raehse because Raehse also fails to teach or suggest an extrusion of a high solid mixture wherein a binder is fed into an extruder downstream of the feed port.

Nowhere does Raehse disclose that a proportion of cleaning or water softening composition particulates remaining in the solid state during extrusion is greater than 20% and includes a citrate salt having a lower limit particle size of 150 μm as required by claim 1.

Because the features of independent claim 1 are neither taught nor suggested by Raehse, Raehse cannot anticipate, and would not have rendered obvious, the features specifically defined in claim 1 and its dependent claims.

For at least these reasons, claims 1, 3-5, 7-9 and 26 are patentably distinct from and/or non-obvious in view of Raehse. Reconsideration and withdrawal of the rejection of the claims under 35 U.S.C. 102(b) relying on Raehse are respectfully requested.

Regarding the rejection of claims 6, 10 and 13 under 35 USC 103(a) as allegedly being unpatentable over Raehse:

Applicants respectfully traverse the rejection of the foregoing claims in view of Raehse.

The Patent Office alleges that the features of claims 6, 10 and 13 are obvious in view of Raehse. Applicants respectfully disagree with the allegations by the Patent Office.

Raehse does not teach or suggest that a proportion of cleaning or water softening composition particulates remaining in the solid state during extrusion is greater than 20%

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and includes a citrate salt having a lower limit particle size of 150 μm as required by independent claim 1, from which claims 6, 10 and 13 depend.

Because these features of independent claim 1 are not taught or suggested by Raehse, Raehse would not have rendered the features of claims 6, 10 and 13 obvious to one of ordinary skill in the art.

In view of the foregoing, reconsideration and withdrawal of this rejection are respectfully requested.

Regarding the rejection of claims 11, 12 and 14 under 35 USC 103(a) as allegedly being unpatentable over Raehse in view of US Patent Publication No. 2002/0015730 to Hoffmann et al (hereinafter "Hoffmann"):

Applicants respectfully traverse the rejection of the foregoing claims in view of Raehse and Hoffmann.

The Patent Office alleges that claims 11, 12 and 14 are obvious in view of Raehse and Hoffmann. Applicants respectfully disagree with the allegations of the Patent Office.

Hoffmann does not remedy the deficiencies of Raehse as set forth above with respect to claim 1, from which claims 11, 12 and 14 depend because Hoffmann does not teach or suggest that a proportion of cleaning or water softening composition particulates remaining in the solid state during extrusion is greater than 20% and includes a citrate salt having a lower limit particle size of 150 μm . Thus, neither Raehse nor Hoffmann, taken singly or in combination, teaches or suggests that a proportion of cleaning or water softening composition particulates remaining in the solid state during extrusion is greater than 20% and includes a citrate salt having a lower limit particle size of the citrate salt of 150 μm as required by independent claim 1.

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Because these features of independent claim 1 are not taught or suggested by Raehse and Hoffmann, taken singly or in combination, these references would not have rendered the features of dependent claim 11, 12 and 14 obvious to one of ordinary skill in the art.

In view of the foregoing, reconsideration and withdrawal of this rejection are respectfully requested.

Should the Examiner in charge of this application believe that telephonic communication with the undersigned would meaningfully advance the prosecution of this application, they are invited to call the undersigned at their earliest convenience.

The early issuance of a *Notice of Allowability* is solicited.

PETITION FOR A ONE-MONTH EXTENSION OF TIME

Applicants respectfully petition for a one-month extension of time in order to permit for the timely entry of this response. The Commissioner is hereby authorized to charge the fee to Deposit Account No. 14-1263 with respect to this petition.

CONDITIONAL AUTHORIZATION FOR FEES

Should any further fee be required by the Commissioner in order to permit the timely entry of this paper, the Commissioner is authorized to charge any such fee to Deposit Account No. 14-1263.

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Respectfully Submitted;

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02 December 2009

Date:

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Enclosures – *Request for Continued Examination*

CERTIFICATION OF TELEFAX TRANSMISSION:

I hereby certify that this paper and any indicated enclosures thereto is being telefax transmitted to the US Patent and Trademark Office to telefax number: 571-273-8300 on the date shown below:

Allyson Ross
Allyson Ross

02-Dec-2009
Date

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